

## **REMARKS**

### **Request to Withdraw Finality**

Applicants respectfully request that the Finality of the previous Office action be withdrawn. The basis of the 35 U.S.C. § 102 rejection was rewritten to include reliance on the O'Byrne (Am.J.Respir.Crit.Care 1999) article. Even though, as discussed below, it fails to provide the teachings for which it is relied on, the Office action has clearly modified the existing rejection here to add reliance on the O'Byrne article for allegedly teaching that treating COPD will inherently treat cystic fibrosis, emphysema or fibrosing alveolitis. The comments in the Office action in support of the 35 U.S.C. §102 rejection rely almost totally on O'Byrne. Thus, the rejection is, in essence, a new ground of rejection. The new ground of rejection was not necessitated by any claim amendments made by applicants. Thus, the Final status of the Office action mailed March 11, 2009, is not warranted and Finality should be withdrawn.

### **The Rejection under 35 U.S.C. §102**

The rejection of claims 9, 11-15, 31 and 32 under 35 U.S.C. §102, as being anticipated by Maesen (Eur.Respir.J.) taking O'Byrne (Am.J.Respir.Crit.Care 1999) in consideration, is respectfully traversed.

The added reliance on the O'Byrne article does not support the rejection. The O'Byrne article (like Maesen) fails to mention anything regarding treating "cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis." O'Byrne and Maesen fail to provide valid support for the allegation in the Office action that "treatment of the symptoms of COPD would inherently treat cystic fibrosis, emphysema or fibrosing alveolitis." As for emphysema, the claims are not directed to treating emphysema.

Maesen teaches that tiotropium bromide can be used to treat COPD. Maesen does not teach that tiotropium bromide can be used to treat any specific symptom of COPD – whether associated with COPD or not. A teaching in a reference that a compound can be used to treat a disease does not provide a description to one of ordinary skill in the art that the compound can separately treat any symptom that might be one that appears with the disease. Although the facts are reversed in Rapoport v. Dement, 254 F.3d 1053, 59 USPQ2d 1215 (Fed. Cir. 2001) – finding that treating one possible symptom does not amount to a teaching to treat the underlying disease or condition – the reasoning is analogously applicable. There is no

reasonable expectation to one of ordinary skill in the art that a compound useful for treating a disease or condition would also be useful for treating a condition that may be a symptom of the underlying disease or condition, even when not associated with the underlying disease or condition.

In any event, Maesen and O'Byrne fail to even support that any of cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis, specifically, are symptoms of COPD. As pointed out above, neither of the references include mention any of these specific terms.

O'Byrne does appear to support that fibrosis, generally, can ultimately occur from COPD. But O'Byrne does not specifically refer to cystic fibrosis, idiopathic lung fibrosis or fibrosing alveolitis. Further, O'Byrne does not support that any particular fibrosis necessarily and inevitably occurs with COPD. Thus, even if it did have specific teachings, it would lack teaching necessary for an inherency argument. For an inherency rejection, the patent law requires that the alleged inherent phenomena necessarily and inevitably occurs, as opposed to a phenomena which might occur, from a given set of conditions; see, e.g., In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); and In re Oelrich, 212 USPQ 323, 326 (CCPA 1981). O'Byrne does not teach that fibrosis (let alone a specific kind) necessarily and inevitably occurs with COPD.

In any event, even if the references supported that cystic fibrosis, idiopathic lung fibrosis or fibrosing alveolitis is a necessary and inevitable symptom of COPD, such a fact would still not support that a method for treating COPD would necessarily treat one of these particular symptoms.

For all of the above reasons, it is urged that the rejection under 35 U.S.C. §102 should be withdrawn.

### **The Rejection under 35 U.S.C. §103**

The rejection of claims 9, 11-23 and 25-32 under 35 U.S.C. §103, as being obvious over Maesen, as applied above, further in view of Skupin (U.S. Patent No. 5,250,286) and Hochrainer (U.S. Patent No. 6,150,418) (optionally also taking O'Byrne (Am.J.Respir.Crit.Care 1999) in consideration), is respectfully traversed.

To the extent this rejection explicitly or implicitly relies on the teachings of O'Byrne, the discussion of O'Byrne from above is incorporated herein by reference. The discussion of Maesen and of the combined teachings of Maesen and O'Byrne from above are also incorporated herein by reference. To summarize, neither of Maesen or O'Byrne provide any

specific mention of cystic fibrosis, idiopathic lung fibrosis or fibrosing alveolitis – let alone a method for treating these conditions.

The Skupin and Hochrainer references were previously relied upon for their teachings regarding the use of certain excipients in connection with active agents administered by inhalation. Applicants maintain their position that carrying out the method of Maesen (with or without the excipients taught in Skupin and/or Hochrainer) will not produce or suggest the claimed invention. As detailed above, Maesen teaches only a method for treating COPD and fails to teach or suggest a “method for treating an inflammatory component of a disease selected from cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis.” Since none of the cited references teaches or suggests a method for treating a disease selected from cystic fibrosis, idiopathic lung fibrosis and fibrosing alveolitis, the combination of references cannot teach or suggest this element of the claimed invention.

The Office action now further alleges that Skupin teaches a method for “treatment of the symptoms of COPD, including cystic fibrosis and emphysema.” However, Skupin does not provide any suggestion that a tiotropium salt can be used to achieve such a method. Skupin relates to the combination of completely unrelated imidazoline and alpha-adrenergic blocking agent compounds for its method. No explanation is provided to support why Skupin’s teachings would suggest to one of ordinary skill in the art that a tiotropium salt could be used to achieve the Skupin method. The compounds taught for the Skupin method are structurally unrelated to tiotropium salts.

Additionally, applicants maintain that no valid reason is established for combining the reference teachings in the manner suggested in the Office action. In response, the Office action points to the basic legal tenet that the motivation for combining the references can be found in the references themselves or in the knowledge generally available to one of ordinary skill in the art. However, the Office action still fails to provide an articulated reason why one of ordinary skill in the art would combine the reference teachings in the manner suggested to support the rejection. The Office action merely states what portions of the individual references teaching are relied on. But no reason for why they would be combined is provided. See, KSR International Co. v. Teleflex Inc., 550 U.S. \_\_, 82 USPQ2d 1385, at 1396 (2007), where the Supreme Court stated: “rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”

Skupin teaches the use of certain excipients in connection with particular alpha-

adrenergic blocking agents. Hochrainer teaches the use of certain excipients in connection with the particular beta-2-stimulator formoterol. Neither of the references provide any reason for one of ordinary skill in the art to reasonably expect that the excipients taught therein would also be useful in combination with a tiotropium salt anticholinergic. The active compounds used in Skupin and Hochrainer are completely distinct from tiotropium both in structure and activity.

For all of the above reasons, it is urged that the rejection under 35 U.S.C. §103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any additional fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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JAS/dap